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375. As set forth above, Fujisawa's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

L. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

376. The GSK Group has engaged in an organization-wide and deliberate scheme to inflate AWP's. The GSK Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs manufactured and/or distributed by the GSK Group for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
GSK GROUP (SmithKline	Advair Diskus	salmeterol- fluticasone	Bronchodilator (Respiratory Agent) Used for treatment of asthma
Beecham, GlaxoSmithKline and Glaxo Wellcome)	Agenerase	amprenavir	Antiviral Agent Used in treatment of HIV infection
	Alkeran	melphalan	Antineoplastic Used to treat ovarian cancer and a certain type of cancer in the bone marrow
	Amerge	naratriptan succinate	Antimigraine Agent Used for treatment of migraine attacks
	Beconase AQ	beclomethasone dipropionate monohydrate	Anti-Inflammatory Agent Used to treat discomfort of hay fever, other allergies, and other nasal problems

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Ceftin	cefuroxime axetil	Antibacterial Agent Used to treat infections caused by bacteria
	Combivir	lamivudine- zidovudine	Antiviral Agent Used in treatment of HIV infection
	Daraprim	pyrimethamine	Antiprotozoal Used for treatment of malaria and other protozoal infections
	Epivir	lamivudine	Antiviral Agent Used in treatment of HIV infection
	Flonase	fluticasone propionate (nasal)	Anti-Inflammatory Agent Used for treatment of allergic and nonallergic rhinitis
	Flovent	fluticasone propionate (inh)	Antiasthmatic (Anti-Inflammatory Agent) Used for treatment of asthma
	Imitrex	sumatriptan or sumatriptan succinate	Antimigraine Agent Used for treatment of migraine attacks or cluster headaches
	Kytril	granisetron hcl	Antiemetic (Gastrointestinal Agent) Used to prevent the nausea and vomiting that may occur after chemotherapy
	Lamictal	lamotrigine	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
	Lanoxin	digoxin	Antiarrhythmic Agent (Cardiovascular Agent) Used to improve the strength and efficiency of the heart, or to control the rate and rhythm of the heartbeat.
	Leukeran	chlorambucil	Alkylating Agent (Antineoplastic) Used to treat cancer of the blood and lymph system
	Mepron	atovaquone	Antiprotozoal Used to treat and to prevent pneumonia
	Myleran	busulfan	Antineoplastic Used to treat some kinds of cancer of the blood.
	Navelbine	vinorelbine tartrate	Antineoplastic Used for treatment of lung cancer
	Paxil	paroxetine hcl	Antianxiety agent; Antidepressant (Psychotherapeutic Agent) Used in the treatment of various psychotherapeutic disorders
	Purinethol	mercaptopurine	Antimetabolite (Antineoplastic) Used to treat some kinds of cancer.

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Relenza	zanamivir	Antiviral Agent Used in the treatment of the infection caused by the flu virus (influenza A and influenza B).
	Retrovir	zidovudine	Antiviral Agent Used for treatment of HIV infection
	Serevent	salmeterol xinofoate	Bronchodilator (Respiratory Agent) Used to treat or prevent symptoms of asthma, chronic bronchitis, emphysema, and other lung diseases
	Trizivir	abacavir sulfate-lamivudine-zidovudine	Antiviral Agent Used for treatment of HIV-1 infection
	Valtrex	valacyclovir hcl	Antiviral Agent Used for treatment of shingles and genital herpes
	Ventolin HFA	albuterol sulfate	Bronchodilator (Respiratory Agent) Used for treatment or prevention of bronchospasm
	Wellbutrin	bupropion hcl	Antidepressant (Psychotherapeutic Agent) Used for treatment of depression
	Zantac	rantidine hydrochloride	Gastrointestinal Agent Used in the treatment of active duodenal ulcer
	Ziagen	abacavir sulfate	Anti Infective Agent Used in the treatment of HIV infection
	Zofran	ondansetron hcl	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zofran ODT	ondansetron	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zovirax	acyclovir	Antiviral Agent Used for treatment of shingles, genital herpes and herpes simplex
	Zyban	bupropion hcl	Antidepressant (Psychotherapeutic Agent) Used to relieve mental depression. Also used to aid in cessation of smoking
		thioguanine	Antineoplastic Used to treat some kinds of cancer

1. The GSK Group Has Been the Target of Government Investigations

377. In connection with its scheme to inflate AWP's, the GSK Group has been investigated by the United States Department of Justice, the Office of Inspector General of the

Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the Attorney General for the State of Nevada, Medicaid Fraud Control Unit.

378. These investigations confirm that the GSK Group has engaged in a deliberate scheme to inflate the published AWP's for its drugs.

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Thus, by its own definition, GSK recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWP's directly affect the payments made by the Class.

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384. The GSK Group tried to maximize spread because it understood that its customers routinely engaged in “spread shopping” – comparing its AWP’s with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread).

385. Perhaps the most flagrant example of the GSK Group’s fraudulent manipulation of AWP’s is found in the documents relating to Glaxo’s Zofran® and SKB’s Kytril®. These two drugs both minimize the nausea associated with chemotherapy, and, prior to the merger of Glaxo and SKB, competed head-to-head in the same market. As detailed below, much of that competition concerned which product could generate *the greater spread*, or profit, for physicians; not over which product was better for patients.

5. Glaxo’s Zofran®

386. A Glaxo marketing document, sent to its sales and marketing personnel via U.S. Mail and interstate wire facilities, advises that they should emphasize to medical providers both the benefits of Zofran® and the financial benefits of the spread. Specifically:

By using a 32 mg bag, the physician provides the most effective dose to the patient and increases his or her profit by \$ _____ in reimbursement as well as paying no upcharges for the bag or admixing

387. A follow-up internal Glaxo memo, dated October 27, 1994, entitled “Zofran Pricing Recommendation,” states: “Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP.” The memo later notes that “Kytril carries a 20% spread between List Price and AWP compared to Zofran which carries a 16 2/3% spread providing SKB with a significant advantage in the clinic setting with respect to reimbursement.” (P007015-P007490, at P007487-P007490).

388. In response to the larger spread being offered on Kytril, this same internal document discusses several options to increase Zofran’s spread “to balance the reimbursement

spread which currently exists between Zofran and the market in which it competes. . . .” The pricing options considered for increasing the “spread” for Zofran® included:

Recommendation #1

4.5% price increase	\$178.97 to \$187.02
Increase AWP	16 2/3% to 20% \$214.76 to \$233.78 (8.5%)
3% Wholesaler Rebate (11/14/94 - 1/31/95)	\$187.02 to \$172.92 (chargeback) \$179.92 to \$167.31 (rebate)

389. In an effort to hide the fact that Glaxo was increasing the spread for Zofran®, Glaxo elected to not only increase its AWP and provide rebates, but to also include a small actual price increase. In describing the reason for an increase in the actual selling price, an internal Glaxo document states:

The recommended multi-tiered modification to current promotion, should also provide an immediate resultant impact to weekly unit sales without being easily intelligible by SKB as to the means by which this was achieved. Thus, providing additional time before a competitive response would be delivered.

390. Glaxo internal documents, however, recognized that as a result of its increasing the spread for Zofran®, SKB would have two options:

- Option 1: Decrease the purchase price of Kytril.
- Option 2: Take a price increase to raise the AWP while maintaining purchase price to generate a higher spread than \$52.00.

(P007015-P007490, at P007489-P007490).

391. In order to increase the spread for Zofran®, Glaxo increased the AWP for a 20 ml injection of Zofran® to \$233.02 in January of 1995. This was discussed in an October 27, 1994 memo entitled “Zofran Pricing Recommendation” and further discussed at a Glaxo pricing committee meeting on November 4, 1994. (P007015-P007490, at P007487-P007490).

392. In February 1995, the *Florida Infusion Chemo Net* reported that Glaxo was increasing the published AWP for Zofran®, but was specifically offering incentives to lower the actual price offered to medical providers, thereby allowing medical providers to seek reimbursement at inflated prices. Specifically:

Effective January 3, 1995. Glaxo has increased the acquisition costs of Zofran injection. The new AWP is set at \$233.02. However, the company has provided incentives to the market place which will ensure that Zofran price to physicians and clinics will be lower than the contractual price available prior to the increase.

Letter from Bliley, Chairman Commerce Committee to Nancy Min DeParle, Sept. 25, 2000 (P007015-P007490, at P007046).

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394. In March 1996, Glaxo again increased the AWP for Zofran® by 4.8%. In response, SKB immediately increased the AWP for Kytril by 4.8%. An internal SKB memo, dated March 21, 1996, entitled "Kytril Price Increase," states:

I recommend a 4.8% price increase effective March 25, 1996 for all Kytril presentations. This is in response to a Glaxo Wellcome price increase of 4.8% for Zofran effective March 8, 1996.

(P007015-P007490, at P007078).

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396. Glaxo also knew that Zofran® products were being marketed based on the spread between the actual cost and the published AWP. For example, when Glaxo introduced the Zofran® premixed IV bag, it used marketing materials which stated:

Convenient
Costs Less Than Vial
Higher AWP
Better Reimbursement

(P007015-007490, at P007243).

397. Other internal Glaxo documents directly compared the "Profit Per Dose" and "Profit as %" and "Profit Per Vial" of Zofran® to Kytril®. These comparisons also identified that in order to increase the spread for Zofran®, Glaxo included "early pay disc" and "rebates" and "incentive."

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401. In a September 27, 2000 article in *USA Today*, Glaxo spokesman Rick Sluder (who received a copy of the October 24, 1994 memo described herein) discussed the issue of the spread and blamed a system that set up a reimbursement method that relies on average wholesale prices which are not actually “representative of actual prices.” Mr. Sluder, admitting that Glaxo changed its wholesale prices to keep up with competitors who changed wholesale prices, stated “We didn’t want to put ourselves at a price disadvantage.” Mr. Sluder also admitted that the marketing of Glaxo drugs is based, in part, on the spread. In fact, he noted that Glaxo’s sales staff is briefed on the price advantages to doctors who bill and get reimbursed based upon the AWP. (E-mail from Clapton to Vaughan dated Sept. 27, 2000 citing “How Drug Makers Influence Medicare Reimbursements to Doctors; WALL STREET JOURNAL (P007501-P007506).

6. SKB’s Kytril

402. According to its internal documents (and prior to selling Kytril®’s global rights to the Roche Group in December 2000), SKB also knew that by creating the spread for Kytril®, it could directly affect the amount of revenue medical providers receive and thereby affect overall demand for Kytril®. Specifically, an August 6, 1996 internal SKB memo stated:

In the clinic setting however, since Medicare reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP.

* * *

From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regimens.

(P007015-P007490, at P007249-P007250).

403. Internal SKB documents reveal how it marketed the spread. One internal document entitled “Price Comparison of Kytril and Zofran for Reimbursement” discussed how

much additional revenue and "spread per patient" a medical provider would make by using Kytril® due to its larger spread. It stated:

Kytril reimbursement for 5 patients treated \$540.00 - Kytril 6 treated patients \$423.12

Difference = \$117.00 every 6 patients.

Use 5ht3 5 times a day = \$2,340.00 month. \$28,080.00 year more!

(P007015-P007490, at P007117).

404. Other internal SKB documents entitled "Cost v. Profit" and "Kytril Profit Model" compare Kytril® and Zofran® to demonstrate how much additional profit/revenue the medical provider will receive by using Kytril®.

7. General Counsel Correspondence Between Glaxo and SKB

405. Most revealing is an exchange of correspondence between counsel for Glaxo and SKB over Zofran® and Kytril® in which each accuse the other of fraud.

406. On February 6, 1995, Timothy D. Proctor, Senior Vice President, General Counsel and Secretary for Glaxo, sent a letter to J. Charles Wakerly, Senior Vice President, Director and General Counsel of SKB informing him of "several issues pertaining to the advertising and marketing of Kytril":

Glaxo's sales representatives have encountered a substantial amount of what appear to be "homemade" Kytril vs. Zofran cost comparisons. It is our understanding that many of these pieces have been generated through a company-provided lap top computer program.

....

In addition, a significant number of these pieces (see Exhibits F-J) contain direct statements or make references as to how institutions can increase their "profits" from Medicare through the use of Kytril. Some even go so far as to recommend that the medical professional use one vial of Kytril for two patients (see Exhibit F) but charge Medicaid for three vials. This raises significant fraud and abuse issues which I am sure you will want to investigate."

(P007015-P007490, at P007123-P007126).

407. On February 22, 1995, Ursualy B. Bartels, Vice President and Associate General Counsel for SKB, wrote in response that SKB was investigating Glaxo's claims and asked whether Glaxo had specific information regarding the improper marketing of Kytril. Mr. Bartels also accused Glaxo of using false and misleading marketing materials regarding Zofran that rely on the medical providers' ability to garner more profit. Specifically, he stated:

Regarding similar concerns, we would like to draw your attention to reports we are receiving from our field force regarding reimbursement issues. In an apparent effort to increase reimbursement to physicians and clinics, effective 1/10/95, Glaxo increased AWP for Zofran by 8.5%, while simultaneously fully discounting this increase to physicians. The latter was accomplished by a 14% rebate available to wholesalers on all non-hospital Zofran sales on the multi-dose vial. *The net effect of these adjustments is to increase the amount of reimbursement available to physicians from Medicare and other third party payors whose reimbursement is based on AWP.* Since the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in AWP was designed to increase revenue per unit to Glaxo. *Absent any other tenable explanation, this adjustment appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive increased reimbursement from Medicare and other third party payors. In fact, we have had numerous verbal reports from the field concerning Glaxo representatives who are now selling Zofran based on the opportunity for physicians to receive a higher reimbursement from Medicare and other third-party payors while the cost to the physician of Zofran has not changed.*

(P007015-007490, at P007478-P007481) (emphasis added).

408. On April 25, 1995, Adrianna L. Carter, Glaxo Assistant General Counsel, responded to SKB's February 22, 1995 letter. Ms. Carter provided, pursuant to SKB's request, numerous additional examples of false and misleading marketing materials concerning "cost comparisons distributed to health care professionals by SmithKline representatives." Ms. Carter also denied SKB's allegations regarding "fraud and abuse" over the price increase of Zofran. However, Ms. Carter did admit that the AWP price increase for Zofran® does not affect the

actual cost to medical providers and that Glaxo's sales representatives were using the "spread" to gain market share. Specifically, Ms. Carter stated:

It is true that, despite a price increase, some physicians and other healthcare professionals will not see the higher price as the result of rebates or other incentives.

* * *

It is also true that our sales representatives have been explaining the relationship between the price and Medicare reimbursement for Zofran to physicians.

* * *

Finally, Ms. Carter stated that despite SKB's assertions that any alleged improper marketing of Kytril would end, "Unfortunately, despite your efforts, these activities are still ongoing."

(P007015-007490, at P007127-P007131).

409. The fact that Glaxo and SKB each accused the other of similar conduct, but neither took any action to bring it to the attention of the public or the appropriate authorities, is evidence that each of them were engaged in an ongoing scheme to defraud the Plaintiffs and Class.

8. Other Improper Incentives

410. In addition to marketing the spread on its products, the GSK Group has also used other methods to induce physicians and other intermediaries to use its drugs such as rebates and free samples in order to increase the spread between acquisition costs and reimbursement.

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412. An advertisement in the *Florida Infusion Chemo net* reveals that SKB created the spread not only by artificially inflating the AWP for Kytril®, but also by providing discounts and rebates. Specifically, the advertisement states:

We have been notified that, effective April 1, 1995, SmithKline's long running promotional rebate for Kytril purchases will come to a very successful conclusion.

(P007015-007490, at P007187).

413. SKB also knew that medical providers were billing Plaintiffs and the Class for a 1 mg single dose vial per patient, but actually were using less than the full single dose per patient. Depending on the weight of a patient, medical providers were able to use less of the drug, *i.e.*, the lighter the patient, the less Kytril® was needed. SKB subsequently introduced a Kytril® 4 mg Multi-Dose vial that allowed medical providers to bill 6 treatments for the cost of 4. For example, an SKB marketing document entitled "Kytril Vial Usage" states, "You can use only three vials of Kytril for four patients." (P007015-007490, at P007068 and P007455).

414. SKB also used other financial incentives to decrease medical providers' costs and thereby increase profits. For example, SKB promised to contribute to research and education programs through the OnCare Foundation if OnCare agreed to use Kytril instead of a competing drug. (P007015-007490, at P007061).

9. Specific GSK Group AWP's Documented by the DOJ

415. In a report published by the DHHS (the "DHHS Report"), the DOJ documented that the published AWP's for various dosages of Zofran and Kytril manufactured by The GSK Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the AWP's identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The GSK Group in the 2001 *Red Book*.

Drug	GSK 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Ondanesetron (Zofran)	\$128.24	\$22.61	\$101.63	450%
Granisetron (Kytril)	\$195.20	\$139.04	56.16	40%

(P006299-P006316).

416. As set forth above, the GSK Group's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

M. Hoffman-LaRoche

417. Hoffman-LaRoche engages in an organization-wide and deliberate scheme to inflate AWP's. Hoffman-LaRoche has stated fraudulent AWP's for all or almost all of its drugs, including, Kytril and CellCept. The specific drugs of Hoffman-LaRoche for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
HOFFMAN-LaRoche	Cellcept	mycophenolate mofetil	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
	Cellcept IV	mycophenolate mofetil hcl	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
	Kytril	granisetron hcl	Antiemetic (Gastrointestinal Agent) Used to prevent the nausea and vomiting that may occur after treatment with anticancer medicines (chemotherapy) or with radiation therapy

1. Hoffman-LaRoche Controls the Published AWP for Its Products

418. Hoffman-LaRoche has controlled and set the AWP's for its pharmaceutical products through direct communications with industry compendia during the Class Period.

2. Inflated Hoffman-LaRoche AWP's From Hoffman LaRoche Price Lists

419. According to the information provided on Hoffman-LaRoche's own website, the published AWP's for Kytril and CellCept were higher than the actual prices provided to wholesalers.

3. Hoffman-LaRoche Provided Free Goods and Other Incentives

420. In addition to marketing the spread, Hoffman-LaRoche has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Hoffman-LaRoche provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

421. As set forth above, Hoffman-LaRoche's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

N. Immunex

422. Immunex engages in an organization-wide and deliberate scheme to inflate AWP's. Immunex has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of Immunex for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
IMMUNEX	Leukine	sargamostin	Antineutropenic Agent Used to help produce bone marrow and white blood cells
	Novantrone	mitoxane hydrochloride	Antineoplastic Used in the treatment of multiple sclerosis and various forms of cancer

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Thioplex	lyophilized thiotepa	Antineoplastic Used in the treatment of ovarian and breast cancer, lymphoma and bladder tumors
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		methotrexate sodium	Antineoplastic Used in the treatment of various forms of cancer

1. Immunex Has Been the Target of Government Investigations

423. In connection with its scheme to inflate AWP's, Immunex has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

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The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class.

5. Specific Immunex AWP's Documented by the DOJ

431. In a report published by the DHHS (the "DHHS Report"), the DOJ documented at least 7 instances where the published AWP's for various dosages of 2 drugs manufactured by Immunex were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 2 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Immunex in the 2001 *Red Book*.

Drug	2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Leucovorin Calcium	\$137.94	\$14.58	\$123.36	846%
Methotrexate Sodium	\$20.48	\$7.10	\$13.38	188%

(P006299-P006316).

432. In a report published by DHHS in 1997, the Department undertook an analysis of the twenty drug codes that represented the largest dollar outlays to the Medicare Program and compared Medicare's payments with the prices available to the physician and supplier communities. For mitoxantrone hydrochloride, sold by Immunex under the brand name Novantrone, the DHHS found that Medicare paid \$172.81, while the actual average wholesale

price was \$142.40, resulting in a spread of 21.36%. "Excessive Medicare Payments for Prescription Drugs" (Dec. 1997).

6. Inflated AWP's From Immunex Price Lists

433. In response to government subpoenas, Immunex produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Immunex has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

434. As set forth above, Immunex's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

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Immunex

effectively hid the AWP spread from Plaintiffs and the Class.

O. The Johnson & Johnson Group (J&J, Centocor and Ortho)

436. The Johnson & Johnson Group engages in an organization-wide and deliberate scheme to inflate AWP's. The Johnson & Johnson Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of the Johnson & Johnson Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
JOHNSON & JOHNSON GROUP (J&J, Janssen, McNeil, Ortho and Centocor)	Aciphex	rabeprazole sodium	Gastric Acid Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of gastroesophageal reflux disease and duodenal ulcers
	Bicitra	sodium citrate & citric acid	Alkalizer Used in the prevention of kidney stones
	Duragesic	fentanyl	Analgesic Used in the treatment of chronic pain
	Elmiron	pentosan polysulfate sodium	Anti-Inflammatory Agent Used for relief of pain associated with interstitial cystitis
	Erycette	erythromycin	Antiacne Agent; Antibacterial Agent Used to help control acne
	Flexeril	cyclobenzaprine	Skeletal Muscle Relaxant (Analgesic) Used in the treatment of muscle spasm associated with musculoskeletal conditions
	Floxin	ofloxacin	Antibacterial Agent Used in the treatment of pneumonia, bronchitis, gonorrhea and certain other infections
	Grifulvin	griseofulvin microsize	Antifungal Agent Used to treat fungus infections of the skin, hair, fingernails, and toenails
	Haldol	haloperidol lactate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
	Haldol Decanoate	haloperidol decanoate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
	Levaquin	levofloxacin	Antibacterial Agent Used to treat bacterial infections in many different parts of the body
	Monistat	miconazole nitrate	Antifungal Agent Used in the treatment of yeast infections
	Mycelex	clotrimazole	Antifungal Agent Used in the treatment of candidiasis and tinea versicolor
	Pancrease	amylase-lipase- protease	Digestant; Enzyme, Pancreatic (Gastrointestinal Agent) Used in the treatment of gastrointestinal disorders

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Parafon Fort	chlorzoxazone	Skeletal Muscle Relaxant (Analgesic) Used to relax certain muscles and relieve the pain and discomfort caused by strains, sprains, or other injuries to muscles
	Polycitra	potassium & sodium citrates w/ citric acid	Alkalizer Used in the prevention of kidney stones
	Procrit	epoetin alfa	Antianemic Used in the treatment of anemia in HIV-infected, cancer or chronic renal failure patients
	Regranex	becaplermin	Biological Response Modifier Used in the treatment of diabetic neuropathic ulcers
	Remicade	infliximab	Anti-Inflammatory Agent; Antirheumatic Agent Used to treat Crohn's disease and rheumatoid arthritis
	Reminyl	galantamine hydrobromide	Cholinesterase Inhibitor (Central Nervous System Agent) Used in the treatment of dementia of the Alzheimer's type
	Renova	tretinoin	Antiacne Agent Used for mitigation of fine wrinkles and other attributes of facial skin
	Retin-A	tretinoin	Antiacne Agent Used to treat acne
	Retin-A Micro	tretinoin microsphere	Antiacne Agent Used to treat acne
	Risperdal	risperidone	Antipsychotic Agent (Psychotherapeutic Agent) Used to treat the symptoms of psychotic disorders
	Spectazole	econazole nitrate	Antifungal Agent Used to treat infections caused by a fungus
	Sporanox	itraconazole	Antifungal Agent Used in the treatment of various fungal infections
	Terazol	terconazole vaginal	Antifungal Agent Used to treat yeast (fungus) infections of the vagina
	Testoderm	testosterone	Androgen; Antianemic Agent; Antineoplastic Used for replacement therapy in males with a deficiency or absence of testosterone

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Tolectin	tolmetin sodium	Antirheumatic Agent Used to relieve some symptoms caused by arthritis
	Topamax	topiramate	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
	Tylox	acetaminophen w/ codeine	Analgesic Used to relieve pain.
	Tylenol with codeine		
	Ultracet	tramadol- acetaminophen	Analgesic Used to relieve pain
	Ultram	tramadol hcl	Analgesic Used for management of pain
	Urispas	flavoxate hydrochloride	Autonomic Nervous System Agent Used in the treatment of symptoms of various urologic disorders.
	Vascor	bepiridil hcl	Antianginal Agent Used to relieve and control angina pectoris and hypertension

1. The Johnson & Johnson Group Has Been the Target of Government Investigations

437. In connection with its scheme to inflate AWP's, the Johnson & Johnson Group has been investigated by the General Accounting Office and the Office of the Attorney general for the Commonwealth of Massachusetts.

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439. The Johnson & Johnson Group has engaged in an ongoing deliberate scheme to inflate AWP's and to market the spread to increase the sales of its products. In a report published by the GAO, federal investigations have documented fraudulently inflated AWP's reported for

epoetin alpha (sold by J&J as Procrit). J&J is identified in various annual *Red Book* publications as one of two sources for epoetin alfa. The other source for epoetin alfa is Defendant Amgen.⁶

440. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services. These massive federal expenditures for epoetin alfa, caused by the J&J Group and Amgen's AWP scheme as well as the inflated cost to Plaintiffs and members of the Class, are even more outrageous given the fact that the research and development of epoetin alfa was originally underwritten by grants from the federal government.⁷

441. By way of further example, the J&J Group has deliberately overstated and continues to overstate the AWP for Remicade®. The published AWP for Remicade® continued to increase each year during the class period. For example, the AWP was listed as \$611.33 for a 100 mg vial of Remicade® as of November 1999, and rose to \$665.65 when listed in the 2001 edition of the *Red Book*. At the same time, J&J deliberately marketed and promoted the sale of Remicade® to physicians based on the availability of inflated payments made by Medicare, assuring them that they would make a significant profit from the purchase of Remicade® as a result of the spread between the actual price to physicians and reimbursement based on the published AWP.

442. The J&J Group created promotional materials and worksheets to allow them to market the spread between the published AWP and the actual selling price to doctors. For example, a publication accessible through Defendants' web sites entitled "Office-Based Infusion Guide" demonstrates Defendants' aggressive marketing of this spread, specifically noting that,

⁶ Amgen markets epoetin alfa for use in the treatment of dialysis patients while the right to market epoetin alfa for all other uses is licensed to Defendant J&J.

⁷ Epogen® and Procrit® are based on different uses of a patented process technology developed at Columbia University with support from grants from the NIH. Columbia licensed their technology to Amgen for Epogen® and to Johnson & Johnson for Procrit®. *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected*, Department Of Health And Human Services National Institutes Of Health, July 2001.

“[d]epending on reimbursement, office-based infusion may provide a financial impact to a physician’s practice.” Moreover, the “Financial Analysis” section of the guide includes a “REMICADE® (infliximab) Financial Impact Worksheet,” which enables doctors see in actual dollars how much additional revenue the use of Remicade® would bring to their practice.

443. As set forth above, the J&J Group’s scheme to inflate its reported AWP’s and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

444.

Table 1

2. J&J Concealed Its AWP Manipulation

445. J&J deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. J&J routinely required that its customers keep secret the prices they were being charged for J&J drugs. (J&J001022; J&J000110; J&J001430; J&J001483).

P. Novartis

446. Novartis engages in an organization-wide and deliberate scheme to inflate AWP's. Novartis has stated fraudulent AWP's for many of its drugs. The specific drugs of Novartis for which relief is sought in this case are set forth in Appendix A.

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
NOVARTIS	Clozaril	clozapine	Antipsychotic (Psychotherapeutic Agent) Used to treat schizophrenia
	Combipatch	estradiol & norethindrone acetate	Hormone Used to treat symptoms of menopause
	Comtan	entacapone	Antidyskinetic Agent Used in combination with levodopa/carbidopa to treat Parkinson's
	Estraderm	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause
	Exelon	rivastigmine tartrate	Cholinesterase Inhibitor (Central Nervous System Agent) Used to treat the symptoms of mild to moderate Alzheimer's disease
	Femara	letrozole	Antineoplastic Used to treat certain types of breast cancer in women
	Lamisil	terbinafine hcl	Antifungal Agent Used to treat fungus infections of the scalp, body, groin, feet, fingernails, and toenails
	Lamprone	clofazimine	Antibacterial Agent Used to treat leprosy
	Lescol	fluvastatin sodium	HMG-CoA Reductase Inhibitor (Cardiovascular Agent) Used to lower levels of cholesterol and other fats in the blood
	Lotensin	benazepril hcl	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Lotensin HCT	benazepril & hctz	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Lotrel	amlodipine besylate-benazepril hcl	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Miacalcin	calcitonin (salmon)	Calcitonin (Hormone) Used to treat Paget's disease of bone. Also used to prevent continuing bone loss in women with postmenopausal osteoporosis and to treat hypercalcemia

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Parlodel	bromocriptine mesylate	Antidyskinetic Agent; Antihyperprolactinemic; Growth Hormone Suppressant Used to treat certain menstrual problems or to stop milk production. Also used to treat infertility and Parkinson's disease
	Ritalin	methylphenidate hcl	Central Nervous System Stimulant Used to treat attention-deficit hyperactivity disorder (ADHD) and narcolepsy
	Starlix	nateglinide	Antidiabetic Agent Used to treat a type of diabetes mellitus (sugar diabetes) called type 2 diabetes
	Tegretol	carbamazepine	Anticonvulsant; Antipsychotic (Psychotherapeutic Agent) Used to control some types of seizures in the treatment of epilepsy
	Trileptal	oxcarbazepine	Central Nervous System Agent; Anticonvulsant Used in the treatment of partial seizures
	Vivelle	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause
	Vivelle-DOT	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause

1. Novartis Has Been the Target of Government Investigations

447. In connection with its scheme to inflate AWP's, Novartis has been investigated by the Office of Inspector General of the Department of Health and Human Services. The Office of the Inspector General published a report for the Department of Health and Human Services in 2000 documenting Novartis' inflated AWP for Aredia, its brand of pamidronate disodium.

2. Inflated Novartis AWP's From Novartis Price Lists

448. As set forth above, Novartis' scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

Q. Pfizer

449. Pfizer engages in an organization-wide and deliberate scheme to inflate AWP's and has stated fraudulent AWP's for many of its drugs. The specific drugs of Pfizer for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
PFIZER	Accupril	quinapril hcl	ACE Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension
	Cardura	doxazosin mesylate	Autonomic Nervous System Agent Used to treat hypertension and benign prostatic hypertrophy
	Estrostep FE	norethindrone-ethinyl estradiol-fe	Oral Contraceptive Also used in the treatment of acne
	Femhrt 1/5	ethinyl estradiol-norethindrone acetate	Estrogen Combination (Hormone) Used in the treatment of menopause and prevention of postmenopausal osteoporosis
	Lipitor	atorvastatin calcium	Antilipemic Agent (Cardiovascular Agent) Used to lower cholesterol
	Nardil	phenelzine sulfate	Antidepressant (Psychotherapeutic Agent) Used in the treatment of depression
	Neurontin	gabapentin	Anticonvulsant Used in the treatment of epilepsy
	Zithromax	azithromycin	Macrolide Antibiotic Agent (Anti-Infective Agent) General antibiotic
	Zoloft	sertraline hcl	Serotonin Reuptake Inhibitor (Psychotherapeutic Agent: Antidepressant) Used in the treatment of depression
	Zyrtec	cetirizine hcl	Antihistamine Used in the treatment of allergic rhinitis

450. Pfizer manufactures and distributes some of the nation's most popular and highest selling brand name drugs.

451. Historically, Pfizer almost never changes the "spread" between the posted AWP and posted WAC for a Pfizer brand name product. Once initially launched, a Pfizer brand name product continues to bear the same difference between the posted AWP and the posted WAC (e.g., 16 2/3%, or 20%, or sometimes 25%).

452. In January 2002, Pfizer announced a prescription drug discount card that would be available to elderly and poor consumers along eligibility criteria similar to that of other discount cards.

453. At the same time, January 2002, Pfizer secretly increased the AWP/WAC spread to 25% for *all* of its brand name drugs. If a drug theretofore had a posted AWP/WAC spread of 20%, it was increased to 25% (something which Pfizer, and indeed all other drug companies, almost never do). If a Pfizer brand name drug already had had a 25% AWP/WAC spread, it remained so.

454. By doing so, Pfizer knew that the purpose and effect of these new listings would be to increase reimbursement payments by end payors by amounts that would be greater than actual transaction costs for other participants in the distribution chain (*i.e.*, wholesalers, distributors, pharmacies and PBMs). Also in doing so, Pfizer knew that the posted AWP's for many of their brand name drugs would become more misrepresentative of actual average wholesale prices given that the increased AWP/WAC spread bore no relation to actual transaction cost changes occurring in the marketplace.

455. Pfizer has been investigated by the Office of the Inspector General of the Department of Human Health Services and has entered into a \$49 million settlement arising from illegal practices with respect to Lipitor. OIG-HSS found that Pfizer has been providing unrestricted educational grants and rebates that were in fact discounts off the purchase price of Lipitor. Pfizer concealed these discounts from states who were entitled to receive the "best price" for Lipitor.

456. The provision of educational grants and rebates on Lipitor also had the effect of inflating the reported AWP.

457. On information and belief, based in part due to the substantial nature of the spreads between AWP and WAC identified in Appendix A, Pfizer has inflated its AWP on other drugs at issue.

R. The Pharmacia Group (Pharmacia and P&U)

458. The Pharmacia Group engages in an organization-wide and deliberate scheme to inflate AWP's. The Pharmacia Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of The Pharmacia Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
PHARMACIA GROUP (Pharmacia and P&U)	Adriamycin	doxorubicin hydrochloride	Antineoplastic Used in the treatment of various forms of cancer
	Adrucil	fluorouracil	Antimetabolite; Antineoplastic Used in the treatment of various forms of cancer
	Amphocin	amphotericin b	Antifungal (Anti-Infective Agent) Used in the treatment of serious fungal infections
	Celebrex	celecoxib	Analgesic; Antirheumatic Agent Used to relieve some symptoms caused by arthritis
	Cleocin-T	clindamycin phosphate (topical)	Antibacterial Agent (Anti-Infective Agent) Used to treat bacterial infections
	Cytosar-U	cytarabine	Antineoplastic Used in the treatment of cancer of the blood
	Depo-Testosterone	testosterone cypionate	Androgen (Hormone) Used to replace hormones or stimulate growth
	Neosar	cyclophosphamide	Alkylating Agent (Antineoplastic) Used in the treatment of various forms of cancer as well as some kidney disease
	Solu-Cortef	hydrocortisone sodium succinate	Anti-Inflammatory Agent; Skin and Mucous Membrane Agent Used to provide relief for inflamed areas of the body. Also used as replacement therapy in adrenocortical insufficiency

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Solu-Medrol	methylprednisolone sodium succinate	Anti-Inflammatory Agent Used to provide relief for inflamed areas of the body. Also used as replacement therapy in adrenocortical insufficiency
	Toposar	etoposide	Antineoplastic Used in the treatment of testicular and lung cancer
	Vincasar	vincristine sulfate	Antineoplastic Used in the treatment of various forms of leukemia and cancer
		bleomycin sulfate	Antineoplastic; Antibiotic Agent (Anti- Infective Agent) Used in the treatment of various forms of cancer

1. The Pharmacia Group Has Been the Target of Government Investigations

459. In connection with its scheme to inflate AWP's, The Pharmacia Group has been investigated by the Department of Justice, the Texas Attorney General, the California Attorney General, the Massachusetts Attorney General, the Attorney General of the State of Connecticut, the Attorney General of the State of New York, and the Department of Health and Human Services Office of Inspector General.

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4. **The Pharmacia Group's AWP Manipulation Benefited Providers at the Expense of the Class**

462. The Pharmacia Group has engaged in an ongoing deliberate scheme to inflate AWP's. According to one member of the Congressional Ways and Means Committee:

The evidence . . . indicates that [Pharmacia & Upjohn] have knowingly and deliberately inflated their representations of the average wholesale price ("AWP"), wholesale acquisition cost ("WAC") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers.

* * *

[T]hese practices must stop and . . . these companies must return the money to the public that is owed because of their abusive practices.

See Extension of Remarks of U.S. Representative Pete Stark in the House of Representatives, October 3, 2000 (P007545-P007547).

463. In a letter dated October 3, 2000 to Pharmacia (with accompanying exhibits), Representative Stark addressed the Pharmacia Group's illegal practices:

The manipulated disparities between your company's reported AWP's and DP's are staggering. For example, in 1997, Pharmacia & Upjohn reported an AWP of \$946.94 for 200 mg. of Adriamycin PFS while offering to sell it to American Oncology Resources (AOR) for \$168.00 and to Comprehensive Cancer Center for \$152.00 (Composite Exhibit "1"). Your company then aggressively marketed its cancer drugs to health care providers by touting financial inducements and other types of incentives. Pharmacia & Upjohn created and marketed the financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers in order to increase the company's market share.

* * *

Pharmacia & Upjohn's own internal documents . . . reveal that the company abused its position as a drug innovator in an initial Phase III FDA clinical trial for a cancer drug used to treat lymphoma (Composite Exhibit "2") (emphasis in original).

" . . . Clinical Research Trials

Initial Phase III Protocol trial for "Oral Idamycin" in lymphomas. This trial will offer AOR \$1.1M [million] in additional revenues. Two hundred twenty-five (225) patients at \$5,000 per patient . . . (emphasis added by Rep. Stark)

The above . . . items are contingent on the signing of the AOR Disease Management Partner Program. AOR's exclusive compliance to the purchase of the products listed in the contract product attachment is also necessary for the above items to be in effect."

The linking of doctor participation in FDA clinical drug trials to their purchase and administration of profit-generating oncology drugs is entirely inconsistent with the objective scientific testing that is essential to the integrity of the trial.

* * *

It is clear that Pharmacia & Upjohn targeted health care providers, who might be potential purchasers, by creating and then touting the windfall profits arising from the price manipulation. For example, Pharmacia & Upjohn routinely reported inflated average wholesale prices for its cancer drug Bleomycin, 15u, as well as direct prices. The actual prices paid by industry insiders was in many years less than half of what Pharmacia & Upjohn represented. Pharmacia & Upjohn reported that the average wholesale price for Bleomycin, 15u, rose from \$292.43 to \$309.98, while the price charged to industry insiders fell by \$43.15 (Composite Exhibit "4").

* * *

Pharmacia & Upjohn reported price increases in October 1997 with full knowledge that the true prices of the drugs were falling. For example, Composite Exhibit "7" reveals that Pharmacia & Upjohn voluntarily lowered its price of Adriamycin PFS 200 mg to \$152.00 while reporting an AWP of \$946.94:

"Dear Willie,

A (VPR) Voluntary Price Reduction will become effective May 9, 1997. The wholesalers have been notified, however it may take two weeks to complete the transition . . ."

Additionally, internal Pharmacia & Upjohn documents secured through the Congressional investigations show that Pharmacia & Upjohn also utilized a large array of other inducements to stimulate product sales. These inducements, including "educational grants" and free goods, were designed to result in a lower net cost to the purchaser while concealing the actual price beneath a high invoice price. Through these means, drug purchasers were provided substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price – the price that corresponded to reported AWPs and inflated reimbursements from the government. Composite Exhibit "8" highlights these inducements:

AOR/PHARMACIA & UPJOHN PARTNERSHIP PROPOSAL:
Medical Education Grants. A \$55,000 grant has been committed for 1997 for the AOR Partnership for excellence package including Education/Disease Management, Research Task Force, AOR Annual Yearbook. A \$40,000 grant to sponsor the AOR monthly teleconference. This sponsorship was committed and complete in February 1997 . . .

PHARMACIA & UPJOHN, INC. INTEROFFICE MEMO:
If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin . . .

Use your "free goods" wisely to compete against other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin (emphasis added by Rep. Stark).

(P007613-P007632).

464. Pharmacia's marketing pitches, as quoted by U.S. Rep. Pete Stark in a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, promoted a physician's ability to profit at the expense of Medicare and its beneficiaries:

PHARMACIA: Some of the drugs on the multi-source list offer you savings of over 75% below list price of the drug. For a drug like Adriamycin, the reduced pricing offers AOR a reimbursement of over \$8,000,000 profit when reimbursed at AWP. The spread from acquisition cost to reimbursement on the multi-source products offered on the contract give AOR a wide margin for profit.

(P007548-P007588).

465. In 1997, Pharmacia sent to a clinic a proposal listing the AWP and the contract price at which several drugs would be sold to the provider. The differences are staggering and just a few are noted below:

Drug	AWP	Suggested New Contract Price
Adriamycin (10 mg)	46.00	7.50
Adriamycin (50 mg)	230.00	37.50
Neosar (2 g)	86.00	18.00
Toposar (1 g)	1,330.75	120.00
Vincasar (2 mg)	741.50	7.50

(P007615).

5. Specific Pharmacia AWP's Documented by the DOJ

466. In a report published by the DHHS, the DOJ documented at least 43 instances where the published AWP's for various dosages of drugs manufactured by The Pharmacia Group

were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Pharmacia Group in the 2001 *Red Book*.

Drug	The Pharmacia Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Amphotercin B	\$36.26	\$16.00	\$20.26	127%
Bleomycin Sulfate	\$309.98 ⁸	\$158.67	\$151.31	96%
Clindamycin Phosphate	\$93.60	\$61.20	\$32.40	53%
Cyclophosphamide	\$6.29	\$3.92	\$2.37	60%
Cytarabine	\$8.98	\$4.06	\$4.92	122%
Doxorubicin HCL	\$1104.13	\$150.86	\$953.27	632%
Etoposide	\$157.65	\$9.47	\$148.18	1,565%
Fluorouracil	\$3.20	\$1.47	\$1.73	118%
Hydrocortisone Sodium Succinate	\$2.00	\$1.55	\$.45	29%
Metholprednisolone Sodium Succinate	\$2.05	\$1.45	\$.60	41%
Testosterone Cypionate	\$17.01	\$11.79	\$5.22	44%
Vincristine Sulfate	\$43.23	\$5.10	\$38.13	748%

467. In OIG report OEI-03-00-00310, the government noted that 20 mg of irinotecan, which according to the *Red Book* is manufactured only by The Pharmacia Group, had a Medicare Median of \$117.81 and a Catalog Median of \$98.63, resulting in a spread of 19.45%. (P006398-P006424).

468. The GAO issued a report entitled "Payments for Covered Outpatient Drugs Exceed Providers' Cost" (GAO-01-1118) wherein it found that irinotecan had an Average AWP

⁸ Calculation based on the AWP listed in the 2000 *Red Book*.

of \$141.32, the Average Widely Available Discount from AWP to physicians for irinotecan was 22.9%, and the drug constituted 2.0% of the total amount of Medicare spending in 1999. (P005546-P005578).

469. As of April 2000, another Pharmacia Group drug, Toposar® (etoposide), had an AWP of \$28.38. The DOJ found that retailers were buying it for \$1.70. (P006299-006316).

470. Similarly, by letter dated September 25, 2000 to the HCFA Administrator, the Chairman of the Commerce Committee revealed that:

[I]n 1998, Pharmacia-Upjohn's Bleomycin had an AWP of \$309.98, but health care providers could purchase it for \$154.85. In 1997, Pharmacia-Upjohn's Vincasar could be purchased for \$7.50, while the AWP was a staggering \$741.50.

See letter dated May 25, 2000 from U.S. Rep. Thomas J. Bliley to Nancy-Ann Min DeParle, HCFA Administrator. (P007015-P007490).

471. Exhibit 1 to U.S. Rep. Pete Stark's September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, reveals that while the AWP for 1 mg of Vincasar® (vincristine sulfate) was \$370.75 in 1997, one physician group's (American Oncology Resources) price in 1997 was only \$4.15. (P007515). Similarly, while the AWP for 2 mg of Vincasar® was \$741.50, AOR's actual pre-April 1997 price was \$7.75 (in fact, The Pharmacia Group had offered to reduce it to \$7.50). *Id.* As of April 2000, Adriamycin had a reported AWP of \$241.36, while the real wholesale price was \$33.43.

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7. The Pharmacia Group Provided Free Goods and Other Incentives

473. In addition to marketing the spread, The Pharmacia Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, The Pharmacia Group provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

474. The government investigators also uncovered an October 3, 1996 internal memorandum wherein Pharmacia told three oncology sales representatives:

Our competitive intelligence tells us that our pricing on Adriamycin, although higher than generics, is in the "ball park" for you to attain the customers Adriamycin business. If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin.

....

You should not have to use "free goods" to steer customer [sic] away from NSS or OTN. OTN and NSS Adriamycin pricing is competitive. Use your "free goods" wisely to compete against